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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/749,386	01/02/2004	Jian-Kang Zhu	247354US20DIV	9333

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EXAMINER	
BAUM, STUART F	

ART UNIT	PAPER NUMBER
1638	

NOTIFICATION DATE	DELIVERY MODE
07/10/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/749,386	ZHU ET AL.	
	Examiner	Art Unit	
	STUART F. BAUM	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36,46 and 51-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36,46 and 51-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The amendment filed 4/14/2008 has been entered.

2. Claims 36, 46 and 51-61 are pending.

Claims 1-35, 37-45 and 47-50 have been canceled.

3. Claims 36, 46 and 51-61, including SEQ ID NO:1 encoding SEQ ID NO:2 are examined in the present office action.

4. Rejections and objections not set forth below are withdrawn.

5. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Claim Objection

6. Claim 52 is objected to for misspelling "thaliana".

Restriction/Election

7. Upon a re-evaluation of the restriction requirement mailed 1/30/2006, the Office is withdrawing the restriction between Groups I and V. Applicant is invited to present claims drawn to the subject matter of Group I and V that may have been previously canceled.

Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 36 and 52-61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a method of increasing the salt tolerance of a plant comprising increasing the expression of a polynucleotide encoding a polypeptide that is at least 95% identical to the amino acid sequence of SEQ ID NO:2, wherein said polypeptide has Na^+/H^+ transporter activity, in said plant compared to the expression of said polynucleotide in the wild-type of said plant.

Applicants' invention is SEQ ID NO:1 (*SOS1*) encoding a Na^+/H^+ antiporter. Mutations in *SOS1* cause a salt-hypersensitive phenotype (page 15, 1st paragraph of "Results" section). *SOS1* was positionally cloned from *Arabidopsis* and is expressed constitutively through-out the plant but is upregulated in response to NaCl treatment. The *Arabidopsis* genomic sequence of SOS1 is disclosed in Figures 7A-7D and corresponds to SEQ ID NO:1 and the encoded protein is disclosed in Figure 3A and corresponds to SEQ ID NO:2. Applicants disclose SEQ ID NO:2 is predicted to encode a transmembrane protein comprising 12 putative transmembrane domains (page 5, Figure 3 legend). Applicants disclose SOS1 is similar to Na^+/H^+ antiporters and present an alignment of the SOS1 protein with two Na^+/H^+ antiporters, NHE1 from Chinese hamster and NhaP from *Pseudomonas aeruginosa* (page 6, Figure 4 legend). Applicants disclose the alignment is based on the N-terminal 450 amino acids of SOS1.

Applicants do not disclose a representative number of nucleic acid sequences that encode a polypeptide that is at least 95% identical to SEQ ID NO:2 wherein the encoded polypeptide has Na^+/H^+ transporter activity.

The Federal Circuit has recently clarified the application of the written description requirement to inventions in the field of biotechnology. See University of California v. Eli Lilly and Co., 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). In summary, the court stated that a written description of an invention requires a precise definition, one that defines the structural features of the chemical genus that distinguishes it from other chemical structures. A definition by function does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. The court goes on to say, "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus." *See University of California v. Eli Lilly and Co.*, 119 F.3d 1559; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997).

Applicants fail to describe a representative number of polynucleotide sequences falling within the scope of the claimed genus of sequences that encode a polypeptide that is at least 95% identical to SEQ ID NO:2 and exhibit Na^+/H^+ transporter activity. Applicants only disclose SEQ ID NO:1. Furthermore, Applicants fail to describe structural features common to members of the claimed genus of polynucleotides. Hence, Applicants fail to meet either prong of the two-prong test set forth by *Eli Lilly*. Furthermore, given the lack of description of the necessary elements essential for the protein encoded by SEQ ID NO:1, it remains unclear what features identify an

Arabidopsis SOS1 protein of SEQ ID NO:2. Since the genus of SOS1 proteins encoded by SEQ ID NO:1 has not been described by specific structural features, the specification fails to provide an adequate written description to support the breath of the claims.

The Office contends that the fact pattern of the instant application is similar to the fact pattern of Example 11A: Percent Identity, "Art-Recognized Structure-Function Correlation Not Present", of the Written Description Guidelines, Revision 1, March 25, 2008. In Example 11A, the specification discloses the reduction to practice of only a single species that encodes SEQ ID NO:2 and has activity X; i.e., SEQ ID NO:1. There are no other drawings or structural formulas disclosed of a nucleic acid that encodes either SEQ ID NO:2 or a polypeptide having 85% sequence identity to SEQ ID NO:2 and activity X. The Office contends that in the instant application, Applicants do not present drawings or structural formulas of the essential domains of a protein having Na^+/H^+ transporter activity that is operable in Applicants' invention. Applicants only present an alignment of the 450 N-terminal amino acids that comprise the 12 putative transmembrane domains (see Figure 4). The Office notes that the protein of SEQ ID NO:2 consists of 1146 amino acids. Therefore, Applicants have not disclosed essential domains that comprise over half of the protein. In addition, the Office notes that Applicants present a phylogenetic tree of other representative Na^+/H^+ antiporters but do not present either boot strap values or percent identities of the other Na^+/H^+ species (see Figure 4). The Office contends it is not clear if SEQ ID NO:2 is in fact a Na^+/H^+ antiporter. Nor have Applicants disclosed other nucleic acid molecules that encode SEQ ID NO:2 that fall within the claimed genus of nucleic acid molecules encoding a protein having at least 95% sequence identity to SEQ ID NO:2 and have Na^+/H^+ transporter activity.

Scope of Enablement

9. Claims 36 and 52-61 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing the salt tolerance of a plant comprising increasing the expression of a polynucleotide encoding a polypeptide of SEQ ID NO:2, wherein said polypeptide has Na^+/H^+ transporter activity and wherein said increasing the expression is by either increasing the copy number of said polynucleotide as compared to the wild type plant or by replacing the native promoter of said polynucleotide with a stronger promoter, does not reasonably provide enablement for said method comprising a polynucleotide encoding a polypeptide exhibiting less than 100% identity with SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 12/12/2007. Applicant's arguments filed 4/14/2008 have been fully considered but they are not persuasive.

Applicants contend the claimed invention is consistent with that reviewed and held enabled by the Board in *Ex parte Bandman* (page 6 or Remarks, 5th paragraph).

The Office contends the Board's opinion in *Ex parte Bandman* is non-precedential.

Applicants state "…determining what sequences fall within or without the scope of the present claims would be readily apparent to the skilled artisan with the present application in hand" (page 7 of Remarks, bottom paragraph). Applicants contend the activity now recited in the claims provides sufficient direction with respect to the scope of the claims and that the skilled

artisan would be able to assess Na^+/H^+ transporter activity given the teaching in the specification (page 8 of Remarks, 1st full paragraph). Applicants contend the attached sequence alignment and discussion pertaining to the same are sufficient for the skilled artisan to identify polynucleotides and polypeptides within the scope of the present invention (page 8 of Remarks, bottom paragraph).

The Office contends the alignment is only for the N-terminal 450 amino acids of the protein and does not address conserved domains of the remaining 650+ C-terminal amino acids. Shi et al (cited by Applicants as providing enablement of the claimed invention, see page 9 of Remarks, bottom paragraph) disclose that several regions in the C-terminal tail are critical for SOS1 function in plant salt tolerance (abstract) but Applicants have not disclosed which regions or domains are essential for the activity of the polypeptide. The Office contends the polypeptide of SEQ ID NO:2 consists of 1146 amino acids which means that the scope of the claims encompasses polypeptides comprising 55 amino acid changes. Therefore, the instant specification fails to provide guidance for which amino acids of the protein encoded by SEQ ID NO:1 can be altered, the type of alteration, and which amino acids must not be changed, to maintain activity of the encoded protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional protein. Therefore, given the breadth of the claims along with the lack of guidance as discussed above, given the state-of-the-art and unpredictability as discussed in the office action mailed 12/12/2007, undue trial and error experimentation would be required to practice the claimed invention.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper time wise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 36, 46, and 51-61 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-11, 19-22, 29-33, 41-44, 52-55, 63-66 of U.S. Patent No. 6,727,408 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are obvious over the claims of Patent No. 6,727,408 B2.

The claims are drawn to a method of increasing the salt tolerance of a plant comprising increasing the expression of a polynucleotide encoding a polypeptide that is at least 95%

identical to the amino acid sequence of SEQ ID NO:2, wherein increasing the expression is by either increasing the copy number of said polynucleotide or by replacing the native promoter of said polynucleotide with a stronger promoter, or wherein the polynucleotide comprises SEQ ID NO:1, or wherein the polynucleotide encodes the polypeptide of SEQ ID NO:2.

Claims 8-11, 19-22, 29-33, 41-44, 52-55, 63-66 of U.S. Patent No. 6,727,408 B2 are drawn to a transgenic plant and method of making a transgenic plant comprising introducing an isolated polynucleotide comprising a nucleic acid sequence comprising SEQ ID NO:1 or encoding the polypeptide of SEQ ID NO:2. The Office contends Applicants' SEQ ID NO:1 exhibits 100% sequence identity with SEQ ID NO:1 from U.S. Patent No. 6,727,408 B2 (sequence search results previously submitted).

Though the claims are not identical, they are not patentably distinct because the claims of U.S. Patent No. 6,727,408 B2 are drawn to a method that is encompassed by the claims of the instant application and would produce a plant that has increased salt tolerance.

Applicant's arguments filed 4/14/2008 have been fully considered but they are not persuasive.

Applicants contend that the third sentence of 35 U.S.C. § 121 is applicable to the present application and precludes a finding of double patenting (page 11 of Remarks, 8th paragraph).

The Office contends, as stated above, that the claims of elected Group V are rejoined with Group I. Therefore, Applicants' arguments are moot.

11. Claims 36, 46, and 51-61 are deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest a method of increasing the salt tolerance of a plant in need thereof

comprising increasing the expression of a polynucleotide encoding a polypeptide that is at least 95% identical to SEQ ID NO:2 wherein increasing the expression is by either increasing the copy number of said polynucleotide or by replacing the native promoter of said polynucleotide with a stronger promoter, or wherein said polynucleotide comprises SEQ ID NO:1.

12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Stuart F. Baum/
Stuart F. Baum Ph.D.
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Art Unit 1638
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